delete "catheter".

Please add the following new claims:

19 ~~25~~. An apparatus for effecting necrosis of a tissue lining in a body cavity comprising:

a catheter comprising a length of flexible tubing having a distal end and a proximal end;

a bladder means for insertion into and distending the body cavity attached to a proximal end;

inflating means connected to said distal end for introducing an inflation medium through said flexible tubing and into said bladder;

a heating means for heating said inflation medium to a temperature sufficient to effect tissue necrosis positioned internal to said bladder; and

control means connected to said distal end for regulating inflation and heating of said bladder.

20 ~~26~~. The apparatus of claim ~~25~~ 19 further comprising a thermocouple for measuring the temperature of said inflation medium positioned internal to said bladder and connected to said control means via an electrical lead.

REMARKS

Reconsideration and allowance of the subject application in light of the above amendment and following marks is hereby requested. The claims pending in this application are 1 to 24. Claims 1 to 20 have been rejected. Claims 21 to 24 have been withdrawn pursuant to a restriction requirement which the Applicants' Attorney preliminarily agreed to. The Applicants hereby affirm the election and wish to proceed with those claims directed to the apparatus of the invention without prejudice to the right to file a divisional application.

The courtesies extended to Applicants and their attorney at the interview conducted October 5, 1989 gratefully acknowledged.

Claims 1 to 3, 7 to 12, 14, 15, 18 and 19 have been amended to more particularly point out what Applicants believe is its invention. Claims 4 and 5 have been cancelled. New claims 25 to 26 have been added.

Claims 2 to 7, 11, 12 and 20 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, in that the Examiner states there is no antecedent basis for "external" and "internal" tubing in the specification. Applicants respectfully disagree with the Examiner's rejection insofar as the specification and associated drawings reference rigid (external) tubing 3 and flexible (internal) tubing 10. It should be understood that the term "rigid" simply means "stiff" in comparison to the "flexible" tubing. Nevertheless, in order to clarify the description, Applicants have amended claims 2, 3, 5 to 7, 11, 12 and 15 to reflect the substitution of the terms "rigid" tubing and "flexible" tubing for "outer" tubing and "inner" tubing, respectively.

Claims 1, 8 and 18 have been rejected as anticipated by Ginsburg et al.

Ginsburg et al. is directed to a balloon-tipped catheter which provides for convectively heating a gas or liquid volume within the balloon to promote restoration and healing of the arterial wall in the region of a stenosis (or obstruction), which region normally suffers from undesired cracking, tearing and stretching caused by contact of the inflated balloon with the vessel wall (column 5, lines 54-56). In addition, as abrupt restenosis or reclosing of the vessel

may occur if torn tissue and plaque become dislodged, it is desirous that the vessel wall treatment result in the smoothing of the stenosed region. In other words, the apparatus of Ginsburg et al. is directed to the restoration and rehabilitation of the arterial wall (column 5, lines 56-58).

Given that Ginsburg et al. is directed to sealing and smoothing the stenosed region (column 3, lines 11-13) of a blood vessel, the degree and length of heating is taught to be quite small. For example, Ginsburg et al. teach the use of an apparatus that provides for convective heat transfer to the interior artery wall because of the limitations inherent in the tissue denaturation which accompanies the use of direct laser irradiation (column 2, lines 40-44). Further, the duration caused by the inflation and heating will typically last from about 30 to 45 seconds, and no more than 10 to 12 seconds in a vessel such as the coronary artery (column 6, lines 2-6). A longer period of inflation, which obviously restricts blood flow, may cause, for example, irreversible damage to the heart (column 6, lines 7-9).

In other words, Ginsburg et al. disclose an apparatus for use in the rehabilitation of the inner walls of blood vessels that must be capable of rapid inflation and heating, and subsequent deflation, in order to achieve the desired sealing and smoothing while minimizing the risk that organs requiring blood flow are damaged.

In order to achieve the desired rapid heating, Ginsburg et al. teach the heating of a block within the balloon by means of a fiber optic waveguide which extends the length of the catheter and is connected at the end opposite the block to an external laser light source, including, for example argon lasers, Nd-Yag lasers and the like (column 2, lines 54-57, and column 4, line 54-59). The use of other heating means,

specifically via an electrical resistance heater, is also disclosed (column 2, lines 58-59) but not described. By contrast, the present invention is directed to the treatment of the tissue wall of body cavities, e.g., the endometrial lining of the uterus, so as to realize cauterization necrosis of the tissue. As noted at page 1, line 14 of the specification, the term necrosis is defined as "the death of cells in tissue." With respect to the endometrium, the intent of such necrosis is to minimize bleeding. Accordingly, the Applicants respectfully submit that the objects of Ginsburg et al. are distinctly different from those of the present invention and those differences are reflected in the structure of the Ginsburg et al. device.

The present invention contemplates that inflation and heating of the bladder will occur for extended periods of time in order to realize necrosis of the body cavity tissue lining. Were this to be attempted in an application such as that to which Ginsburg et al. is directed, irreversible damage to the inner vessel wall and to various body organs would occur. Moreover, blood vessels are not body cavities in the sense that they are filled with blood in a living patient.

Accordingly, Applicants respectfully submit that the rejection of claims 1, 8 and 18 which are directed to an apparatus for necroses of the tissue lining of a body cavity is improper and should be withdrawn.

Claims 2 to 5, 9 to 12 and 20 have been rejected under 35 U.S.C. § 103 as being unpatentable over Ginsburg et al. in view of Kozinski. As discussed above, the disclosure of Ginsburg et al. is not sufficient to teach or suggest to one of ordinary skill in the art Applicants' device for effecting necrosis of tissue lining a body cavity.

Kozinski discloses a therapeutic apparatus for applying dry heat to body cavities comprising an applicator that is introduced into the body cavity while deflated and which is subsequently inflated and heated by means of circulating heated air. Kozinski does not disclose an applicator which conforms to the shape of a body cavity. Kozinski further teaches that the air, which is not an efficient conductor of heat, must be circulated through the applicator and that the tube connecting the applicator to the heated air source is preferably insulated to protect it from undesired burning of tissue regions (column 3, lines 17-20). By contrast, the present invention does not heat the inflation medium until it is in the bladder. Accordingly, no special insulation is required, as is necessary for both Kozinski and for Ginsburg et al. (column 4, lines 24-26). Further, there is no suggestion that the combination of Ginsburg et al. and Kozinski may achieve the convenient and inexpensive apparatus of the present invention.

Claims 6 and 7 have been rejected under 35 U.S.C. § 103 as being unpatentable over Ginsburg et al. in view of Kozinski as applied to claims 2 to 5, 9 to 12 and 20, and further in view of Landman et al.

Landman et al. comprises an elongated catheter having an inflatable balloon associated with the distal portion of the catheter and a valve member associated proximally with at least one lumen communicating with the volume of the balloon. Liquid is introduced into the lumen via a pumping means comprising a hypodermic barrel and a three-way valve to control fluid flow. As with Ginsburg et al., Landman et al. is directed to an apparatus for use in connection with the treatment of blood carrying arteries and veins of the body. As Landman et al. is utilized in blood vessels, a means to purge air from the

bladder is required in order that an accidental rupture does not release air into the blood stream. Such an air-purging system is not required in the present invention's treatment of body cavities. As there was no suggestion to combine Ginsburg, et al. and Kezinski, there is no suggestion that a combination of these references with Landman.

Claims 13 and 15 to 17 have been rejected under 35 U.S.C. 103 as being unpatentable over Ginsburg et al. in view of Solar. Solar includes time control means for regulating the inflation and deflation of a balloon attached to an end of a catheter inserted into the ventricle of a human heart. Such regulation is required in Solar because it is directed to mimicking the pumping action of the superior and inferior vena cava. There is no suggestion that this timed regulation could be combined with Ginsburg et al. to achieve the control means taught in the present invention, particularly given the results that are sought by Solar, i.e., heart pumping action, versus those of the present invention; the controlled inflation and heating of the bladder.

Claim 14 has been rejected under 35 U.S.C. § 103 as being unpatentable over Ginsburg et al. in view of Solar as applied to claims 13 and 15 to 17 and further in view of Wood. Wood comprises an applicator for applying dry heat to body cavities and includes a thermocouple and temperature display and means for controlling the heating action. Again, there is no suggestion to combine Ginsburg et al. with Solar and/or Wood to achieve the present invention. With regard to Wood it is noted that container 32 is "expansible" and includes heating means 40 within copper tube 41.

Claim 19 has been rejected under 35 U.S.C. 103 as being unpatentable over Ginsburg et al. in view of Moore et al. Moore comprises an endoscope having scale gradations thereon to

indicate the depth of insertion of the catheter into the body. There is no suggestion that such a form of endoscope could be combined with the catheter of Ginsburg et al. to achieve the present invention.

Finally, as noted above, Wood includes a heating means within an expandable member and similarly German Patent No. 895,046 of record (translation provided by Examiner at the October 5, 1989 Interview) discloses a device for heat treatment of internal organs that include a heating element in an expandable member that can be inserted into body cavities including the uterus. The German device is said to be intended for use in diathermy type treatments indicating that "burning" is to be avoided (Translation p. 2, lines 2-10) and the Wood device has similar applications. In contrast, Applicants' device is specifically designed to effect necrosis of tissue, i.e., substantial burning. Nothing found in either Wood or the German reference even remotely suggests that this type of device could be provided with a heating means that can effect tissue necrosis.

Applicants believe that this application is now in condition for allowance and such action is respectfully requested. If the Examiner believes that the prosecution of

this case could be advanced by contact with Applicants' attorney he is invited to contact the undersigned at the number given below.

Respectfully submitted,

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